Minutes of the SMC Committee Meeting

Tuesday 03 December 2024

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Mr Graeme Bryson Professor James Dear Dr Colm Doody Ms Fiona Davies Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Robin McNaught Dr Catriona McMahon Dr Emma Morrison Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Ms Caroline Whitworth
Observers:	Ms Melissa Davidson Ms Irene Fazakerley Ms Claire Henderson-Hughes Ms Mariam Mustapha Mr Juan Soto
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mrs Jennifer Dickson Mr Roy Foot Mr Scott Mahony

	Mrs Mairi McConnochie Ms Rosie Murray Mr Richard O'Connell Ms Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait
Apologies:	Mr Andrew Bone Ms Ailsa Brown Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Ms Fiona Green Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Mr Anthony McDavitt Mrs Pauline McGuire Ms Eileidh McIntosh Dr Paul Neary Ms Sharon Cowell-Smith Professor Alison Strath Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **Invited Observers** • **Ms Melissa Davidson,** newly appointed pharmacist, SMC. • **Ms Claire Henderson-Hughes**, NDC Member. • **Ms Mariam Mustapha**, Senior Clinical Pharmacist, NHS Forth Valley. • **Mr Juan Soto,** NDC Member.
2.	**Declarations of Interest**
2.1	The Chair reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (Tuesday 05 November 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 05 November 2024 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	Nothing to report.
4.2	**Deferred Advice**
	fosdenopterin powder for solution for injection (Nulibry®) Sentynl Therapeutics Inc SMC2624 – Ultra orphan medicine In August 2024, SMC reviewed fosdenopterin powder for solution for injection (Nulibry®), for the treatment of patients with molybdenum cofactor deficiency (MoCD) Type A. SMC advice was withheld at the time pending product availability. The product is now available and advice will be issued to NHS Boards and ADTCs on Friday 06 December 2024 and published on the SMC website on Monday 13 January 2025.
5.	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	vamorolone oral suspension (Agamree®) Santhera Pharmaceuticals (Deutschland) GmbH SMC2721

	A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines. A personal non financial specific declaration of interest was recorded in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the joint Patient Group submission, and provide clarification on any outstanding issues. The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a joint Patient Group submission from Muscular Dystrophy UK, Duchenne UK & Action Duchenne. Detailed discussion followed and, after a vote of the members, it was decided that vamorolone (Agamree®), should be **accepted for use** within NHSScotland. Indication under review: treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older. In a randomised, double-blind, phase IIb study, treatment with vamorolone resulted in a significant improvement in the change in time to stand from supine (TTSTAND) velocity and change in 6-minute walk test (6MWT) distance between baseline and week 24, compared with placebo. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday, 13 January 2025.
6.2	<u>sirolimus gel (Hyftor®) Plusultra pharma SMC2710</u> A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines.

	Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. A representative of the Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Tuberous Sclerosis Association. Detailed discussion followed and, after a vote of the members, it was decided sirolimus (Hyftor®), should **be accepted for use** within NHSScotland. Indication under review: for the treatment of facial angiofibroma associated with tuberous sclerosis complex in adults and paediatric patients aged 6 years and older. In a randomised phase III study, sirolimus gel demonstrated a statistically significant improvement in facial angiofibromas at week 12 compared with placebo. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting The SMC advice will be published on the SMC website on Monday, 13 January 2025.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	Nothing to report.
10.	**Closed Session**
10.1	**Update on medicines accepted via streamlined approach**
	Full Submissions relugolix, estradiol, norethisterone acetate film-coated tablets (Ryego®) Gedeon Richter SMC2666 **Accepted for use** within NHSScotland.

	Indication under review: In adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis. Relugolix, estradiol, norethisterone acetate film-coated tablets (Ryeqo®), compared with placebo, resulted in statistically and clinically significant improvements in treatment response (menstrual and non-menstrual pelvic pain) after 24 weeks in women with moderate-to-severe pain associated with endometriosis. The SMC advice will be published on the SMC website on Monday 13 January 2025.
	<u>danicopan film-coated tablets (Voydeya®) Alexion Pharmaceuticals Inc SMC2675</u> **Accepted for restricted use** within NHSScotland. **Indication under review:** As an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria who have residual haemolytic anaemia. SMC restriction: under the advice of the national PNH service. In a randomised phase III study, danicopan, as an add-on treatment to C5 inhibitor, was associated with a statistically significant improvement in haemoglobin concentrations at week 12 compared with placebo. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. The SMC advice will be published on the SMC website on Monday 13 January 2025.
	<u>iptacopan hard capsules (Fabhalta®) Novartis Pharmaceuticals UK Limited SMC2676</u> **Accepted for restricted use** within NHSScotland. **Indication under review:** As monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia. SMC restriction: under the advice of the national PNH service. In an open-label phase III study, iptacopan significantly improved haemoglobin levels by at least 2 g/dL and significantly increased the number of patients with haemoglobin levels greater than or equal to 12 g/dL in patients with PNH who had persistent anaemia despite treatment with anti-C5 treatment. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. The SMC advice will be published on the SMC website on Monday 13 January 2025.

	Abbreviated Submissions
	<u>ciclosporin 0.9 mg/mL eye drops, solution in single-dose container (Cequa®) Sun Pharma UK Limited SMC2739</u> **Accepted for restricted use** within NHSScotland. **Indication under review:** treatment of moderate-to-severe Dry Eye Disease (keratoconjunctivitis sicca) in adult patients who have not responded adequately to artificial tears. SMC restriction: severe keratitis in adult patients with Dry Eye Disease. Cequa® is a new formulation of ciclosporin eye drops, with limited net budget impact. The SMC advice will be published on the SMC website on Monday 13 January 2025.
	<u>risankizumab solution for injection in cartridge and concentrate for solution for infusion (Skyrizi®) AbbVie Ltd SMC2686</u> **Accepted for use** within NHSScotland. **Indication under review:** for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy. Risankizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. The SMC advice will be published on the SMC website on Monday 13 January 2025.
	<u>ublituximab concentrate for solution for infusion (Briumvi®) Neuraxpharm UK Ltd SMC2731</u> **Accepted for restricted use** within NHSScotland. **Indication under review**: treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. SMC restriction: treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

	Ublituximab offers an additional treatment choice in the therapeutic class of anti-CD20 monoclonal antibodies. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. The SMC advice will be published on the SMC website on Monday 13 January 2025.
	<u>crovalimab solution for injection/infusion (Piasky®) Roche Products Limited SMC2728</u> **Accepted for restricted use** within NHSScotland. **Indication under review:** as monotherapy for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity. • In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months. SMC restriction: under the advice of the national PNH service Crovalimab offers an additional treatment choice in the therapeutic class of complement C5 inhibitors. Another complement C5 inhibitor was accepted for restricted use under the orphan equivalent process. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. The SMC advice will be published on the SMC website on Monday 13 January 2025.
10.2	**Non-Submissions**
	<u>bictegravir / emtricitabine / tenofovir alafenamide 30 mg / 120 mg / 15 mg film-coated tablet (Biktarvy®) Gilead Sciences Ltd SMC2760</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation bictegravir / emtricitabine / tenofovir alafenamide (Biktarvy®) is not recommended for use within NHSScotland. **Indication under review:** treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg

	without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result, we cannot recommend its use within NHSScotland.
	<u>rozanolixizumab solution for injection (Rystiggo®) UCB Pharma Limited SMC2761</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation rozanolixizumab (Rystiggo®) is not recommended for use within NHSScotland. **Indication under review:** as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result, we cannot recommend its use within NHSScotland. The holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future.
11.	**Voting / Decisions**
12.	**Any Other Business in Closed Session**
12.1	An Education Session was presented for: • SMC Collaborations
13.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 07 January 2025.